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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,448	12/30/2003	Jeff Ondrla	1671-0285	2398

28078 7590 03/23/2007

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111 MONUMENT CIRCLE
SUITE 3250
INDIANAPOLIS, IN 46204

EXAMINER	
BLANCO, JAVIER G	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,448	ONDRLA ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 14, 2006 has been entered.

Response to Amendment

2. Applicants' cancellation of claims 1, 3, 7, and 12-18 in the reply filed on December 14, 2006 is acknowledged.

3. Applicants' addition of claims 19-37 in the reply filed on December 14, 2006 is acknowledged.

Claim Objections

4. Claim 33 is objected to because of the following informality: please substitute "the internal bore" (see line 2) with --the internal bore of the mounting element-- (i.e., to avoid confusion with internal bore 16 of stem 12). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 28, "the fastener" (see line 2) lacks antecedent basis.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 19-37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bahler (WO 2001/22905; previously cited by the Examiner). For English translation see US 6,749,637 B1.

Referring to Figure 1, Bahler discloses a shoulder joint prosthesis comprising:

(a) A stem (stem 13 of shaft 11), said stem defining a first coupler bore having a proximal bore segment (**first interpretation:** bore 25; **second interpretation:** bore 35, when piece 33 is inserted into bore 25) and a distal bore segment (threaded bore 31), with a ledge (**first interpretation:** ledge 29; **second interpretation:** ledge between 35 and 31/39) located between the proximal bore segment and the distal bore segment;

(b) A joint component (cap 65) having a bearing surface (surface 75) and defining a second coupler bore (conical indentation 83);

(c) A mounting element (directional piece 41) having (i) a proximal portion (conical face 45) received within said second coupler bore of said joint component in a friction fit manner, and (ii) a spherical articulating portion (articulating face 43) received within said first coupler bore of said stem;

(d) A fastener (screw 53) located within said proximal bore segment and said distal bore segment, and having an externally threaded shaft (threaded portion 57) which engages internal threads located within said distal bore segment (threaded bore 31) of said first coupler bore.

The bearing surface of said joint component mates with a glenoid component (85). The "interior wall portion" could be: **(i)** a portion of the interior wall of bore 25; **(ii)** a portion of wall 34 (it will be "interior" once piece 33 is inserted into bore 25); and/or **(iii)** a portion of the interior wall of bore 35. Any of these "interior wall portions" extends from a proximal surface of the stem in a straight line. Also, articulating face 43 touches the internal bore around substantially an entire perimeter of the internal bore defined by the intersection of a plane (note: the "plane" is not defined in the claim language) with the internal bore.

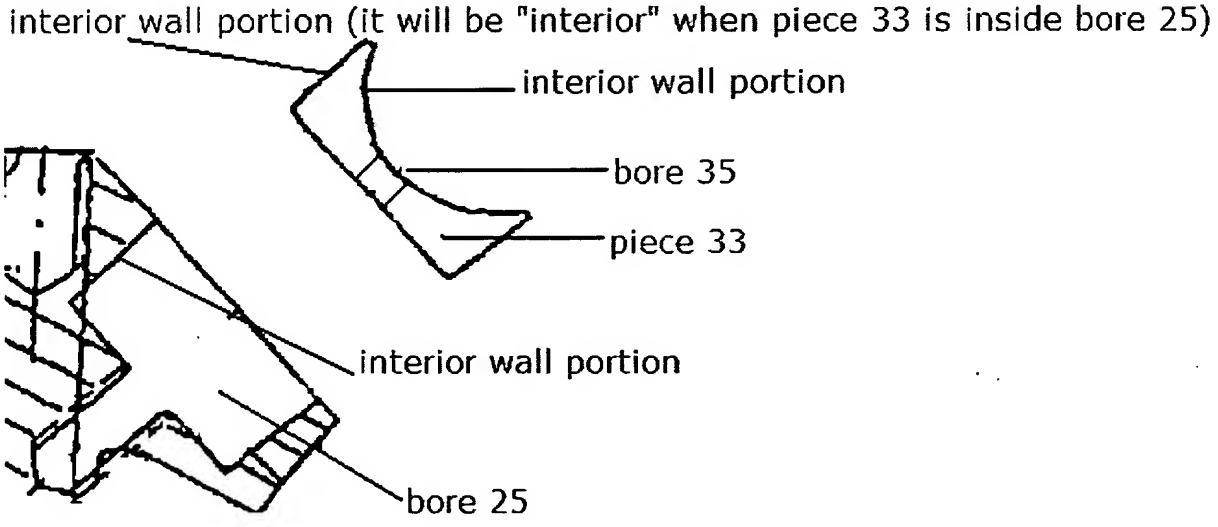
Response to Arguments

9. With regards to the 102(b) rejection based on Bahler (WO 2001/22905; previously cited by the Examiner), Applicants' arguments filed December 14, 2006 have been fully considered but they are not persuasive.

a. With regards to claims 19, 27, and 32, the Applicants argue that Bahler does not disclose or suggest: **(i)** the functional limitation "*configured to force the spherical articulating portion against the interior wall*", **(ii)** the limitation "*the spherical articulating portion of the mounting*

element touches the linearly extending interior wall of the stem", and **(iii)** the functional limitation "*the spherical articulating portion configured for press-fit engagement with the internal bore such that the spherical articulating portion touches the internal bore around substantially an entire perimeter of the bore*". The Examiner respectfully disagrees.

Screw 53 is configured to force articulating face 43 against the interior wall of bore 25 (via piece 33) or the interior wall of bore 35 (when piece 33 is inserted into bore 25). The interior wall portion could be: **(i)** a portion of the interior wall of bore 25; **(ii)** a portion of wall 34 (it will be "interior" once piece 33 is inserted into bore 25); and/or **(iii)** a portion of the interior wall of bore 35. Any of these "interior wall portions" extends from a proximal surface of the stem in a straight line. Also, articulating face 43 touches the internal bore around substantially an entire perimeter of the internal bore defined by the intersection of a plane (note: the "plane" is not defined in the claim language) with the internal bore. Below is a representation of Bahler's Figure 1:



10. Claims 27-37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS).

Referring to Figures 1-8 (particularly Figures 3-5), Glien et al. disclose a joint prosthesis comprising:

a. A stem (stem 12) having a bone engagement portion and a surface facing the mating component of the joint, said surface defining a tapered bore (cavity 14 is tapered at 15, 16, 17, and its distal end);

b. A head component (head 40) having a bearing surface (see Figures 3-5) and a tapered cavity (tapered cavity 41);

c. A mounting element (character 20) having a proximal portion (tapered block 21, 28) *configured for engagement* (emphasis added to functional language) with said head component and an articulating portion (hemispherical ball joint 23) defining a spherical bearing surface sized *to be received* (emphasis added to functional language) within said tapered bore and *to form* (emphasis added to functional language) a friction-fit engagement with said bore when said articulating portion is pushed into said bore, the mounting element further having a passageway (cavity 24) through said mounting element with an inner bearing surface (surfaces 25, 26, and tapered surface between the proximal end and distal end of cavity 24) at said articulating portion; and

d. A screw (screw 30) extending from said mounting element *for engagement* (emphasis added to functional language) to the stem when said articulating portion is disposed within said tapered bore. Said screw comprises a cylindrical rod 31 having threaded end 33 formed therein. Said screw further includes an underside *configured for articulating contact* (emphasis added to

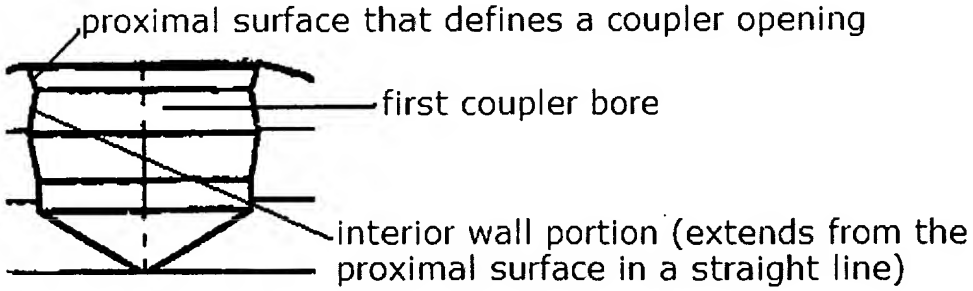
functional language) with said inner bearing surface (surfaces 25, 26, and tapered surface between the proximal end and distal end of cavity 24) of the mounting element. The spherical bearing surface of said mounting element for contacting said bore to permit movement of said mounting element in multiple degrees of freedom (see Figures).

Response to Arguments

11. With regards to the 102(b) rejection based on Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS), Applicants' arguments filed December 14, 2006 have been fully considered but they are not persuasive.

a. With regards to claims 27 and 32, the Applicants argue that Glien et al. does not disclose or suggest: **(i)** the limitation (from claim 27) "*an interior wall portion located within the first coupler bore that extends from the proximal surface in a straight line, and wherein the spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line*", and **(ii)** the limitation (from claim 32) "*a fastener coupled with the mounting element and with the stem*". The Examiner respectfully disagrees.

b. Regarding claim 27, it should be noted that the claim language requires "a proximal surface that defines a coupler opening". Below is a representation of Glien et al.'s Figure 3:



Based on this representation (and as seen in Figures 4 and 5), the "*spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line*".

c. Regarding claim 32, fastener (screw 30) is "*coupled with the mounting element and with the stem*" (clearly shown in Figures 4 and 5).

12. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS).

Referring to Figures 1-9 (particularly Figures 1-3), Leonard et al. disclose a joint prosthesis comprising:

a. A stem (stem 1) having a bone engagement portion (rod 2) and a surface (frontal face 4 of metaphysical section 3) facing the mating component of the joint, said surface defining a bore (cavity 7) and a threaded bore (threaded bore 8) aligned with said bore;

b. A head component (head 20) having a bearing surface (see Figures 1-3) and a tapered cavity (tapered cavity 21);

c. A mounting elèment (tapered swivel 12 + hemispherical ball joint 10) having a proximal portion (tapered swivel 12) *configured for engagement* (emphasis added to functional language) with said head component (see columns 6 and 7) and an articulating portion (hemispherical ball joint 10) defining a spherical bearing surface sized *to be received* (emphasis added to functional language) within said bore (see columns 5 and 6) and *to form* (emphasis added to functional language) a friction-fit engagement (see column 6, lines 25-31) with said bore when said articulating portion is pushed into said bore, the mounting element further having a passageway

(cavity 14) through said mounting element with an inner hemispherical bearing surface (hemispherical surface 10b) at said articulating portion; and

d. A screw (locking unit 16) extending from said mounting element *for engagement* (emphasis added to functional language) to said threaded bore (see columns 6 and 7) when said articulating portion is disposed within said bore. Said screw comprises a cylindrical rod 17 having threaded end 17a formed therein. Said screw further includes hemispherical ball joint 18 (underside of head 19) *configured for articulating contact* (emphasis added to functional language) with internal/inner hemispherical surface 10b of hemispherical ball joint 10. The spherical bearing surface of said mounting element for contacting said bore to permit movement of said mounting element in multiple degrees of freedom (see column 8, line 61 to column 9, line 24). The method for mounting said joint component to a bone is disclosed at column 8, line 48 to column 9, line 36. The method (particularly, position adjustment) could be performed with or without using a trial implant (see column 9, lines 37-48).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1) and Bahler (WO 2001/22905; previously cited by the Examiner).

With regards to independent claim 19, Leonard et al. disclose the invention as claimed (see 102(b) rejection above) except for particularly disclosing a ledge located between the first bore portion and the second bore portion. However, this is well known in the art. For example, both Horber (see US 6,818,019 for English translation) and Bahler disclose a stem having a coupling bore and a ledge (see Horber's Figures 1 and 10: character 23; see Bahler's Figure 1: character 29) located between a first bore portion and a second bore portion of said coupler bore in order to allow the articulating surface of a mounting element/ articulation body to rotate about an axis, while preventing a rolling movement of the articulation body in the articulation cavity. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a stem having a coupling bore and a ledge located between a first bore portion and a second bore portion of said coupler bore, as taught by Horber and Bahler, with the stem of Leonard et al., in order to allow the articulating surface of a mounting element/ articulation body to rotate about an axis, while preventing a rolling movement of the articulation body in the articulation cavity.

15. Claims 27-31 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1) and Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS).

With regards to claims 27, Leonard et al. disclose the invention as claimed (see 102(b) rejection above) except for particularly disclosing an interior wall portion located within the first coupler bore that extends from the proximal surface in a straight line, and wherein the articulating portion of the mounting element touches the interior wall portion at a point along the straight line. However, this is well known in the art. For example, both Horber (see US

6,818,019 for English translation) and Glien et al. disclose a joint prosthesis comprising an interior wall portion (see Horber's Figures 1 and 10: character 25; see Glien et al.'s Figure 3: character 16) located within a first coupler bore that extends from the proximal surface in a straight line, and wherein the articulating portion of the mounting element touches the interior wall portion at a point along the straight line in order to permit movement of the articulating surface of a mounting element/ articulation body in multiple degrees of freedom, while preventing a rolling movement of the articulation body in the articulation cavity. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a joint prosthesis comprising an interior wall portion located within a first coupler bore that extends from the proximal surface in a straight line, and wherein the articulating portion of the mounting element touches the interior wall portion at a point along the straight line, as taught by Horber and Glien et al., with the stem of Leonard et al., in order to permit movement of the articulating surface of a mounting element/ articulation body in multiple degrees of freedom, while preventing a rolling movement of the articulation body in the articulation cavity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for

the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

March 7, 2007

David H. Willse
Primary Examiner